DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 5 19

Stephen Rogers, Ph.D.
Director, Regulatory Affairs
The Agricultural Group of Monsanto Company
700 Chesterfield Parkway North
Chesterfield, MO 63198

Dear Dr. Rogers:

This is in regard to your genetically modified tomato with a delayed ripening trait about which you initiated consultations with the agency in September of 1993. The new tomato variety has been modified for delayed ripening by expression of the enzyme aminocyclopropane carboxylic acid deaminase from the soil bacterium *Pseudomonas chloraphis*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new tomato variety on August 26, 1994. On September 19, 1994, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by Monsanto to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded that the new tomato variety is not materially different in composition, safety, or any other relevant parameter from tomato varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0002 and that will be maintained in the Office of Premarket Approval.

Based on the description of the data and information presented during the consultations, the new tomato variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning this product at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition